SLOVENSKI STANDARD
oSIST prEN IEC 63120:2021

01-marec-2021

Prenovitev medicinske električne opreme, medicinskih električnih sistemov in podsestavov ter ponovna uporaba komponent za podaljšanje življenjskega cikla

Refurbishment of medical electrical equipment, medical electrical systems and sub-assemblies and reuse of components as part of the extended life-cycle

Aufarbeitung von medizinischen elektrischen Geräten, medizinischen elektrischen Systemen und Baugruppen und Wiederverwendung von Bauteilen als Teil des verlängerten Lebenszyklus

Reconditionnement des appareils électromédicaux, des systèmes et sous-ensembles électromédicaux et réutilisation des composants dans le cadre du cycle de vie étendu

Ta slovenski standard je istoveten z: **prEN IEC 63120:2021**

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general
13.020.60	Življenjski ciklusi izdelkov	Product life-cycles

oSIST prEN IEC 63120:2021 **en**

62A/1424/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 63120 ED1**	
DATE OF CIRCULATION: **2021-01-08**	CLOSING DATE FOR VOTING: **2021-04-02**
SUPERSEDES DOCUMENTS: **62A/1379/CDV, 62A/1399A/RVC**	

IEC SC 62A: COMMON ASPECTS OF ELECTRICAL EQUIPMENT USED IN MEDICAL PRACTICE	
SECRETARIAT: USA	SECRETARY: Ms Hae choe
OF INTEREST TO THE FOLLOWING COMMITTEES: TC 56,SC 62B,SC 62C,SC 62D	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.
FUNCTIONS CONCERNED: ☐ EMC ☐ ENVIRONMENT ☒ QUALITY ASSURANCE ☒ SAFETY	
☒ SUBMITTED FOR CENELEC PARALLEL VOTING **Attention IEC-CENELEC parallel voting** The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting. The CENELEC members are invited to vote through the CENELEC online voting system.	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING

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Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:

Extension of the life cycle of medical electrical equipment, medical electrical systems and sub-assemblies by refurbishing and by re-use of components

PROPOSED STABILITY DATE: 2025

NOTE FROM TC/SC OFFICERS:

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

Extension of the life cycle of medical electrical equipment, medical electrical systems and sub-assemblies by refurbishing and by re-use of components

FOREWORD

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The text of this standard is based on the following documents:

FDIS	Report on voting
62A/XXXX/FDIS	62A/XXXX/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this document the following print types are used:

– requirements and definitions: roman type;

– informative material, such as notes, examples and references: smaller type;

– TERMS DEFINED IN CLAUSE 3 OR AS NOTED: SMALL CAPITALS.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

The National Committees are requested to note that for this document the stability date is 2025.

THIS TEXT IS INCLUDED FOR THE INFORMATION OF THE NATIONAL COMMITTEES AND WILL BE DELETED AT THE PUBLICATION STAGE.

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INTRODUCTION

The aim of this document is to support a MANUFACTURER or a REFURBISHER of MEDICAL ELECTRICAL EQUIPMENT (MEE) and MEDICAL ELECTRICAL SYSTEMS (MES) with a framework within which experience, insight and judgment are applied systematically to manage the HAZARDS associated with REFURBISHMENT activities. It deals with PROCESSES for managing HAZARDS, primarily to the patient, but also the operator and other persons.

The principles of RISK MANAGEMENT for Medical Devices which are specified in ISO 14971 are not modified by this document; the aim of REFURBISHMENT is to contribute to circular economy aspects for MEDICAL ELECTRICAL EQUIPMENT (MEE) or MEDICAL ELECTRICAL SYSTEMS (MES) and to support material efficiency to improve the environmental aspects of MEE and MES. This document specifies the necessary additional RISK MANAGEMENT steps. These are used to extend the life cycle of MEE/MES to at least one second lifetime. While circular economy plays a key role to contribute to the environmental impact, BASIC SAFETY and ESSENTIAL PERFORMANCE of MEE/MES may not be compromised.

A key element for refurbishing of MEE/MES is that they are constructed and manufactured to an environmental conscious design that enables REFURBISHMENT. IEC 60601-1-9 or IEC 62430 can be substantial contributors to this goal.

REFURBISHERS of used MEE/MES should be certified under a quality management system such as ISO 13485:2016 or equivalent for REFURBISHMENT.

Compliance with ISO 13485 is not sufficient to demonstrate that a RISK MANAGEMENT PROCESS compliant with ISO 14971 requirements is performed for REFURBISHMENT of MEE/MES. There can be no investigation to IEC 60601 series without the MANUFACTURER'S RISK MANAGEMENT FILE being available.

An important aspect of REFURBISHMENT is that normally the ownership of the MEE/MES can change from the first owner to the REFURBISHER and then to a second owner whereas for repair, maintenance and servicing the ownership does not change normally.

SUB-ASSEMBLIES refurbished according to this document can also be used for new MEE/MES. MANUFACTURER of the MEE/MES should consider the obligation to inform his customers about the status of RE-USED COMPONENTS or refurbished SUB-ASSEMBLIES in the MEE/MES delivered.

Figure 1 shows the relation between COMPONENTS, SUB-ASSEMBLIES, MEE or MES where the main difference is that for COMPONENTS, the MANUFACTURER does not have the design control making it impossible for a MANUFACTURER to refurbish COMPONENTS. The MANUFACTURER can only RE-USE COMPONENTS.

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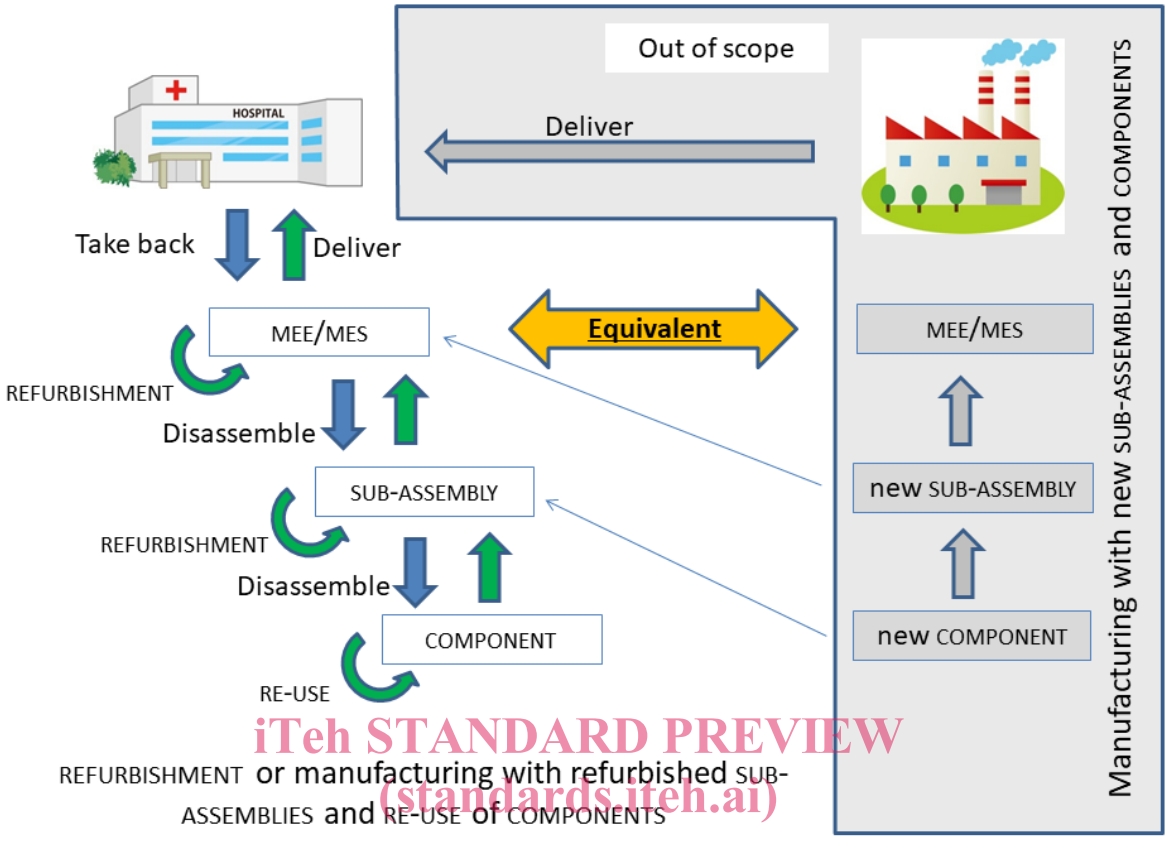

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145 **Figure 1 – Relationship between MES, MEE, SUB-ASSEMBLY and COMPONENTS in the context**
146 **of this document**

147

148 For the purposes of this document, the auxiliary verb:
149
150 – “shall” means that conformance with a requirement or a test is mandatory for conformance
151 with this document;
152 – “should” means that conformance with a requirement or a test is recommended but is not
153 mandatory for conformance with this document;
154 – “may” is used to describe permission (e.g. a permissible way to achieve conformance with a
155 requirement or test);
156 – "can" is used to describe a possibility or capability; and
157 – "must" is used to express an external constraint.

EXTENSION OF THE LIFE CYCLE OF MEDICAL ELECTRICAL EQUIPMENT, MEDICAL ELECTRICAL SYSTEMS AND SUB-ASSEMBLIES BY REFURBISHING AND BY RE-USE OF COMPONENTS

1 Scope

This document describes the REFURBISHMENT PROCESS following risk management concepts for the REFURBISHMENT of MEDICAL ELECTRICAL EQUIPMENT (MEE), MEDICAL ELECTRICAL SYSTEMS (MES) - which are covered by the IEC 60601 series of standards - or SUB-ASSEMBLIES and the RE-USE of COMPONENTS as a possibility for an extended life cycle for MEE/MES.

Applying this PROCESS to used MEE/MES and SUB-ASSEMBLIES as defined in this document ensures compliance to BASIC SAFETY and ESSENTIAL PERFORMANCE of the refurbished MEE and MES including their SUB-ASSEMBLIES.

This document also covers REFURBISHED SUB-ASSEMBLIES for re-use during the EXTENDED LIFE CYCLE of ME EQUIPMENT and ME SYSTEMS, and RE-USE of used COMPONENTS.

This document does not cover

- medical imaging equipment in the scope of IEC 63077:2019, including their SUB-ASSEMBLIES and COMPONENTS;
- repair, maintenance and servicing of ME EQUIPMENT or ME SYSTEM covered by IEC 60601-1 and IEC 62353;
- unauthorized modification of ME EQUIPMENT or ME SYSTEM or parts of such equipment/systems;
- environmental conscious design covered by IEC 60601-1-9 or IEC 62430;
- environmental aspects covered by the ISO TC 207 standards and waste treatment covered by IEC TC 111 standards;
- REFURBISHMENT of limited multiple use devices or parts of such devices;
- REFURBISHMENT of single use devices or parts of such devices;
- REFURBISHMENT of COMPONENTS.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012 + IEC 60601-1:2005/AMD1:2012/AMD2:2020[1]

IEC 62304, *Medical device software – Software life cycle processes*

IEC 62309:2004, *Dependability of products containing reused parts – Requirements for functionality and tests*

ISO 13485:2016, *Medical devices – Quality management systems – Requirements for regulatory purposes*

[1] At publication stage [footnote to be deleted before publication]

ISO 14971:2019, *Medical devices – Application of risk management to medical devices*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
BASIC SAFETY
freedom from unacceptable RISK directly caused by physical HAZARDS when ME EQUIPMENT is used under normal condition and single fault condition

Note 1 to entry: "Normal condition" and "single fault condition" are defined terms in IEC 60601-1.

[SOURCE: IEC 60601-1:2005+A1:2012+A2:2020: 3.10, modified –Note 1 to entry added.]

3.2
COMPONENT
element of a SUB-ASSEMBLY that cannot be meaningfully decomposed any further

Note 1 to entry: Example: A separate part of a printed circuit board assembly that performs a circuit function, e.g. a resistor, a capacitor, a transistor, etc.

3.3
ESSENTIAL PERFORMANCE
performance of a clinical function, other than that related to BASIC SAFETY, where loss or degradation beyond the limits specified by the MANUFACTURER results in an unacceptable RISK

Note 1 to entry: ESSENTIAL PERFORMANCE is most easily understood by considering whether its absence or degradation would result in an unacceptable RISK.

[SOURCE: IEC 60601-1:2005+A1:2012+A2:2020: 3.27]

3.4
EXPECTED SERVICE LIFE
time period specified by the MANUFACTURER during which the ME EQUIPMENT, ME SYSTEM or SUB-ASSEMBLIES are expected to remain safe for use (i.e. maintain BASIC SAFETY and ESSENTIAL PERFORMANCE)

Note 1 to entry: Maintenance can be necessary during the EXPECTED SERVICE LIFE.

[SOURCE: IEC 60601-1:2005+A1:2012+A2:2020: 3.28]

3.5
EXTENDED SERVICE LIFE
time period specified by the REFURBISHER during which the ME EQUIPMENT, ME SYSTEM or SUB-ASSEMBLIES are expected to remain safe for use (i.e. maintain BASIC SAFETY and ESSENTIAL PERFORMANCE) after REFURBISHMENT

Note 1 to entry: Maintenance can be necessary during the EXTENDED SERVICE LIFE.

3.6
LIFE CYCLE
series of all phases in the life of a medical device, from the initial conception to final decommissioning and disposal

[SOURCE: ISO/IEC Guide 63:2019, 3.5]

3.7
EXTENDED LIFE CYCLE
all phases in the life of a MEE/MES, from the initial conception, REFURBISHMENT, to final decommissioning and disposal

3.8
HARM
injury or damage to the health of people, or damage to property or the environment

[SOURCE: ISO/IEC Guide 63:2019, 3.1]

3.9
HAZARD
potential source of HARM

[SOURCE: ISO/IEC Guide 63:2019, 3.2]

3.10
HAZARDOUS SITUATION
circumstance in which people, property, or the environment is/are exposed to one or more hazards

[SOURCE: ISO/IEC Guide 63:2019, 3.3]

3.11
MANUFACTURER
natural or legal person with responsibility for the design, manufacture, packaging, or labelling of ME EQUIPMENT, assembling an ME SYSTEM, or adapting ME EQUIPMENT or an ME SYSTEM, regardless of whether these operations are performed by that person or on that person's behalf by a third party

Note 1 to entry: ISO 13485 defines “labelling” as written, printed or graphic matter

– affixed to a medical device or any of its containers or wrappers, or

– accompanying a medical device,

related to identification, technical description, and use of the medical device, but excluding shipping documents. In this standard, that material is described as markings and accompanying documents.

Note 2 to entry: “Adapting” includes making substantial modifications to ME EQUIPMENT or an ME SYSTEM already in use.

Note 3 to entry: In some jurisdictions, the responsible organization can be considered a MANUFACTURER when involved in the activities described.

Note 4 to entry: Adapted from ISO 14971: 2019, definition 3.9.

Note 5 to entry: “Accompanying documents” and “responsible organization” are defined terms in IEC 60601-1.

[SOURCE: IEC 60601-1:2005+A1:2012+A2:2020, 3.55 modified: Note 1: bibliographic reference removed, Note 5 to entry added]